REMARKS

Applicant and applicant's attorney express appreciation to the Examiner for the courtesies extended during the recent interview held on June 4, 2007, in which claim 1 and new claim 28 were discussed. Reconsideration and allowance for the above-identified application are now respectfully requested. Claims 1-4, 6-15 and 28-33 are pending, wherein claims 1–4, 6–11 and 13-15 have been amended, claims 5 and 16-22 have been cancelled, and new claims 28-33 have been added.

A. Election/Restrictions

Applicant notes the Examiner's comments regarding the "Election/Restriction". In particular, the Office Action states that the Applicant's attempt to link claims 11 and 16 to claim 1 is improper and that these claims have not been examined. In response, Applicant reserves the right to pursue these claims in a divisional or related application. Moreover, claims 16-22 have been cancelled. However, Applicant respectfully requests rejoinder of claims 11-13 upon the allowance of claim 1, as a method of manufacturing or using a patentable composition or device is *per se* patentable and requires no additional search of the art since any such method claims incorporate the same combination of elements as claim 1. Accordingly, Applicant believes the claims as now presented create no additional burden on the examiner.

B. Claim rejections Under 35 U.S.C. §112 and §101

The Examiner rejects claims 1–10, 14, and 15 under 35 U.S.C §112, second paragraph for indefiniteness. The Office Action states that claims 1–10, 14, and 15 are indefinite for attempting to claim a "system." Similarly, claims 1–10, 14, and 15 have been rejected under 35 U.S.C. §101 as failing to claim eligible subject matter because the claims attempt to claim a "system." While Applicant disagrees that any of claims 1–10, 14, or 15 are indefinite or claim ineligible subject matter, Applicant has amended claims 1–10, 14, and 15 to recite "an implant device" in order to further prosecution. Support for this amendment can be found in the application at ¶¶ [0005]–[0009], ¶ [0012], and Figures 1–3. Applicant submits that the term "implant device" is not indefinite and constitutes patentable subject matter as it is a composition of matter and/or an article of manufacture. Thus, Applicant respectfully requests that the rejections under §112, second paragraph and §101 be withdrawn.

C. Rejection Under 35 U.S.C. §102(b)

The Office Action rejects claims 1–7, 9–10, and 14–15 under 35 U.S.C. § 102(b) as being anticipated over the following references: *Levy* (U.S. Patent No. 5,292,253), *Chen* (U.S. Patent

No. 5,707,962), *Ashman* (U.S. Patent No. 4,728,570), *Tormala* (U.S. Patent No. 4,863,472), and *Silvererg* (U.S. Patent No.4,755,184). The following discussion first provides a brief review of the invention as currently claimed and then addresses each of the cited §102(b) references in the order presented in the Office Action.

The claimed invention is directed to an implant device for promoting bone growth in a bone defect. The implant device has a dry water-absorbing gelatinizable outer cover that encapsulates a bone growth promoting material within an interior of the implant device. The outer cover encases the bone growth promoting material so that it can be placed in a bone defect without separating and falling out. Because the device is initially dry, it can be easily handled and shipped. In addition, the covering is made from a material that is gelatinizable upon contact with water. Upon contact with water, the covering becomes sticky and gelatinous such that it adheres to bone or tissue in a bone defect. This feature allows a practitioner to place the device in a bone defect and have the device more reliably stay in place than would be possible with a similar device that does not become gelatinous and sticky (*e.g.*, upon contact with aqueous bodily fluids, such as blood, saliva, plasma, mucous, etc. that are typically found in the body during a surgical procedure). That is quite different than, for example, a conventional cellulose gauze or collagen suture material that does not become gelatinous and sticky upon contact with water but merely decomposes in the body over a prolonged period of time (*e.g.*, through slow enzymatic activity). Such a material would not provide the desired adhesiveness when initially placed in a bone defect.

To better distinguish Applicant's invention, claim 1 has been amended to require that the covering is "dry" and that it forms an outer cover that encapsulates the bone growth promoting material. Support for a "dry" cover can be found in the application at ¶ [0029]. Support for the concept of a covering that "encapsulates the bone growth promoting material" can be found at ¶ [0029] and Figures 1 and 2. Claim 1 has also been amended to require a gelatinizable material "that becomes sticky and gelatinous upon contact with water." Support for this amendment can be found at ¶ [0010]. In addition, claim 1 has been amended to recite a list of bone growth promoting materials. This limitation was previously claimed in original claim 5.

Newly added independent claim 28 also requires a "dry covering" that "encapsulates the bone growth promoting material" and a covering made from a "gelatinizable material that forms a sticky gelatinous material upon contact with water." The limitations of claim 28 can be found in currently amended claim 1 and original claim 16. New claims 29–32 depend from claim 28

and recite features recited in original claims 2, 5, 17, and 19. New claim 33 also depends from claim 28 and support for this claim can be found in the application at ¶ [0006].

None of the references cited in the Office Action teach the invention as now claimed in claims 1 and 28. In particular, none of the references teach a device with a "dry covering" that "encapsulates a bone growth promoting material" and that "becomes sticky and gelatinous upon contact with water." *Levy* teaches filling a periodontal pocket with a gelatinous material and welding the material to bone or tissue using a YAG laser. (*See* col. 1, line 64 – col. 2, line 14.) *Levy* does not teach or suggest an implant device comprising a dry covering that encapsulates a bone growth promoting material or the use of a covering that becomes sticky and gelatinous upon contact with water.

Chen discloses an implant made from a porous matrix (col. 1, lines 65-66). Every example describes the device as a "sponge." (*See* Examples 1-6.) *Chen* does not teach a dry covering that encapsulates a bone growth promoting material and that becomes gelatinous and sticky upon contact with water. While *Chen* does disclose gelatin (col. 3, line 4), the gelatin is blended with bone granules to form a "matrix," not a dry covering that encapsulates a bone growth promoting material and that becomes sticky and gelatinous upon contact with water as required by claims 1 and 28.

Ashman teaches "a porous matrix of a mass of biologically-compatible polymeric particles, the particles bonded together to form a unitary prosthetic implant." (*See* abstract.) *Ashman* does not teach a "dry covering" that "encapsulates a bone growth promoting material" and that "becomes sticky and gelatinous upon contact with water".

Tormala teaches the use of a "supporting structure" that includes a "bone graft powder." The supporting structure "contains at least one orifice, whose size is bigger than the size of the pores" and is "bigger than the size of the bone graft powder particles." Thus, the supporting structure disclosed in *Tormala* teaches away from a dry covering that "encapsulates the bone growth promoting material" and "that becomes sticky and gelatinous upon contact with water."

Silverberg teaches a hollow casing made of a resorbable material that is filled with a filling material for bones. (*See* abstract.) *Silverberg* teaches that the resorbable casing is made from PGA, bovine collagen (an absorbable suture material) or cellulose (*see* col. 3, lines 35–46). However, neither *Silverberg* nor any of the reverences discussed above teach a dry covering made from a material that becomes "sticky and gelatinous upon contact with water." Materials such as collagen and cellulose can be converted into a gelatinizable material using chemical

(*e.g.*, enzymatic) processes known in the art. However, cellulose and collagen in their natural forms do not become gelatinous and sticky upon contact with water. Neither does PGA, which is a hydrophobic synthetic polymer. For example, cotton shirts made of cellulose and sutures made of collagen or PGA do not become gelatinous upon contact with water. If they did, cotton shirts could not be laundered but would disintegrate in the wash, and sutures would quickly fall apart and allow wounds or incisions to gape open upon prolonged contact with subcutaneous blood or other fluid. Sutures, in fact, persist for weeks or months in solid form before they are either resorbed or removed. Otherwise, they would lack their desired utility of closing incisions and allowing healing, which can take weeks or months depending on the severity of the incision. Had *Silvergerg* contemplated the use of a material that becomes sticky and gelatinous upon contact with water, he most certainly would not have taught the use of PGA, suture grade collagen, or cellulose.

As pointed out by the Examiner during the interview, cellulose and collagen only become gelatinous when left in the body for an extended period of time (*e.g.*, months). However, these materials can become gelatinous in the body because the body has biological agents such as enzymes that break down the cellulose or collagen using chemical reactions. Claim 1 has been amended to require that the cover be made of a material "that becomes sticky and gelatinous upon contact with water." Cellulose and collagen require chemical degradation to become gelatinous. In contrast, the materials claimed in the present invention (*e.g.*, *oxidized* cellulose) become "sticky and gelatinous" by merely absorbing water. The time it takes for a material that is gelatinizable upon contact with water to become gelatinous is much shorter than a material that must be chemically degraded by enzymes in a human body (*e.g.*, minutes or seconds rather than weeks or months). Materials that become gelatinous upon contact with water are advantageous in the present invention because they allow the covering to become sticky and gelatinous during a dental or other surgical procedure. This feature facilitates the placement and retention of the implant in a bone defect.

In conclusion, none of the references of record teach a "dry covering" that "encapsulates a bone growth promoting material" and "becomes sticky and gelatinous upon contact with water" either explicitly or inherently. Therefore, Applicant respectfully requests that the rejections under §102(b) be withdrawn.

D. Rejection Under 35 U.S.C. §103

Claims 1–10, 14 and 15 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Silverberg* taken with *Tomala*, in view of *Levy* and *Vyakarnam* (U.S. Patent No. 6,306,424). As discussed above, claim 1 has been amended to require a "dry covering" made of a material "that becomes sticky and gelatinous upon contact with water" and that "encapsulates the bone growth promoting material." None of the references alone or in combination teach or suggest the claimed invention when viewed as a whole. While some of the references teach the use of a gelatin (*e.g.*, *Chen* col. 3, line 4), these references mix a gelatinous material directly with the bone material to make a matrix. In contrast, claims 1 and 28 require a covering made of a gelatinizable material. There is no teaching, suggestion, motivation, or explicit reason for one of skill in the art to use the materials of the matrix as a cover. On the other hand, *Silverberg* appears to teach away from a covering that becomes sticky and gelatinous by instead disclosing a sheath made of materials that do not become sticky and gelatinous upon contact with water. Thus, Applicant submits that claims 1 and 28 as now presented are patentable over the art of record.

Claims 2–4, 6–10, 14–15, and 29–33 all depend from either claim 1 or 28. Therefore, claims 2–4, 6–10, 14–15, and 29–33 are patentable for at least the same reasons that claims 1 and 28 are patentable.

In the event that Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by examiner amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 29th day of June 2007.

Respectfully submitted,

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